DEC 22 2000

BECKMAN COULTER

Summary of Safety & Effectiveness
SYNCHRON® Systems Ammonia (AMM) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

October 10, 2000

3.0 **Device Name(s):**

3.1 **Proprietary Names**

SYNCHRON® Systems Ammonia (AMM) Reagent

3.2 **Classification Name**

Ammonia (21CFR §862.1065)

4.0 **Predicate Device(s):**

SYNCHRON Systems Reagent	Predicate	Manufacturer	Docket Number
SYNCHRON® Systems Ammonia (AMM)	SYNCHRON® Systems Ammonia (AMM)	Beckman Coulter, Inc.	K984402

5.0 **Description:**

The SYNCHRON System Ammonia Reagent is designed for optimal performance on the SYNCHRON LX® System. It is intended for use in the quantitative determination of ammonia in plasma.

6.0 **Intended Use:**

The SYNCHRON® Systems Ammonia (AMM) Reagent, in conjunction with SYNCHRON® Systems Ammonia Calibrators, is intended for the quantitative determination of ammonia concentration in plasma on SYNCHRON® Systems.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicate identified in Section 4.0 of this summary.

SYNCHRON® Systems Ammonia Reagent	SIMILARITIES	
	Reagent Formulation	Same as predicate
	Reagent Volume	
	Analytical Wavelength	
	Reaction Time	
	Kit and container label	
	DIFFERENCES	
	Sample Volume	Candidate SYNCHRON Ammonia assay requires 40 µL of sample Vs SYNCHRON Ammonia assay that requires 25 µL of sample

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, and imprecision experiments.

Method Comparison Study Results
SYNCHRON® Systems Digoxin (DIGN) Reagent

SYNCHRON DIGN Reagent	Sample Type	Slope	Intercept (µmol/L)	r	n	Predicate Method
SYNCHRON LX System with 40 µL sample size	Plasma	1.014	-0.70	0.9985	56	SYNCHRON LX System with 25 µL sample size

Estimated Within-Run Imprecision

SYNCHRON System	Sample	Mean (µmol/L)	S.D. (µmol/L)	%C.V.	N
CX	Level 1	47	1.6	3.4	15
	Level 2	130	1.5	1.2	15
	Level 3	621	2.6	0.4	15
LX	Level 1	47	2.5	5.4	15
	Level 2	130	2.1	1.6	15
	Level 3	621	5.0	0.8	15

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2000

Ms. Lucinda Stockert
Staff Regulatory Specialist
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Re: K003196
Trade Name: SYNCHRON® Systems Ammonia Reagent
Regulatory Class: I reserved
Product Code: JIF
Dated: October 10, 2000
Received: October 12, 2000

Dear Ms. Stockert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003196

Device Name: **SYNCHRON® Systems**
Ammonia Reagent

Indications for Use:

The SYNCHRON® Systems Ammonia (AMM) Reagent, when used in conjunction with SYNCHRON® Systems Ammonia Calibrators, is intended for the quantitative determination of ammonia in plasma on Beckman Coulter's SYNCHRON Systems.

Clinical Significance:

Circulatory ammonia level in normal individuals is relatively low despite the fact that ammonia is continuously produced from dietary and amino acid metabolism. Monitoring blood ammonia levels can be useful in the diagnosis of hepatic encephalopathy and hepatic coma in the terminal stages of liver cirrhosis, hepatic failure, acute and subacute necrosis, and Reye's syndrome. Hyperammonemia in infants may be an indicator of inherited deficiencies of the urea cycle metabolic pathway.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003196

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96